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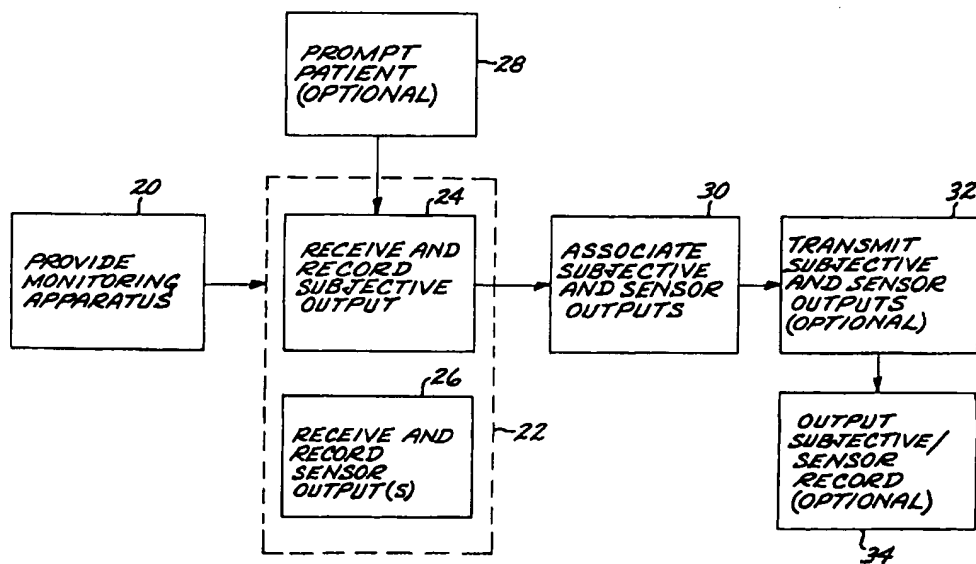
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(54) Title: **CORRELATION OF SENSOR SIGNALS WITH SUBJECTIVE INFORMATION IN PATIENT MONITORING**



(57) Abstract: Health information for a patient is organized and correlated by recording a subjective-information input from the patient as a recorded patient subjective-information record, monitoring and recording the condition of the patient with a sensor as a recorded patient sensor record, and automatically associating the recorded patient subjective record and the recorded patient sensor record. The association may be accomplished through the use of respective subjective-information time markers and sensor time markers to produce a subjective/sensor record.

CORRELATION OF SENSOR SIGNALS WITH SUBJECTIVE INFORMATION IN PATIENT MONITORING

This invention relates to the monitoring of patients and, more particularly, to the correlation of sensor information and subjective information relating to the monitoring.

BACKGROUND OF THE INVENTION

Patient diaries are important tools in analyzing the medical conditions of patients whose health is being monitored, particularly patients who are ambulatory or otherwise not under continuous observation in a hospital setting. Sensors record objective physiological health evidence, but a subjective diary record of what the patient is doing and what the patient feels and observes during events of interest provides the physician with information that aids in interpreting the sensor record and making a diagnosis. Together, the sensor record and the diary record may allow the physician to understand whether a particular physiological condition is caused by the patient's activities or by some other cause. The sensor record may also be correlated with the patient's sensations during events of interest.

The subjective patient diary may be kept in a written form or a tape recorded form. In either case, problems often arise with the making of the diary record. In some situations, the patient is not consciously aware of any need to make a diary entry and therefore does not make a diary record. Where the patient is consciously aware of a physiological problem and a diary record is made, the diary entry may be made at a time well after the events of interest. The patient is often preoccupied with the events as they occur because the events themselves may be, or may be perceived to be, life threatening as in the case of heart problems, so that a written diary entry cannot easily be made contemporaneously with the events. At a time after the events, the patient may forget to make the diary entry. If the patient does remember to make the entry at a later time, the patient may err in the indicated time of the sensations that prompted the entry or err in recalling the sequence or timing of the sensations. At a later time, the patient's recollection of the most important sensations may fail, so that incorrect

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and/or nonrelevant information may be recorded, and the most important information not be recorded.

Patient diaries are therefore important information in understanding and diagnosing patients who are being monitored, but the necessary entries are often missing or erroneous in some respect. There is therefore a need for an improved approach to the maintaining of patient diaries of monitored patients in conjunction with the sensor record. The present invention fulfills this need, and further provides related advantages.

10

SUMMARY OF THE INVENTION

The present invention provides a subjective record of a monitored patient in which the subjective record is made contemporaneously with the sensor record of events of interest. The subjective record may include, for example, an audio record or a written record. The subjective record, which includes the patient diary and may include other subjective information as well, is automatically correlated with the objective sensor record. The patient is freed of the need to make a separate written or recorded diary, and the physician has a complete and accurate sensor record and correlated subjective record. The subjective record input in audio form is often more complete than a separate written diary record might be, because many persons are able to communicate their sensations more readily verbally than in writing. Additionally, an audio record and diary can often capture inflections, sounds of straining, or the like that cannot be readily communicated in writing.

In accordance with the invention, a method of organizing and correlating health information for a patient comprises the steps of recording a subjective input from the patient as a recorded patient subjective record, monitoring and recording the condition of the patient with a sensor as a recorded patient sensor record, and automatically associating the recorded patient subjective record and the recorded patient sensor record. In one embodiment, the subjective record, is recorded with a subjective record time marker, the sensor record is recorded with a sensor time marker, and the subjective record and the sensor record are associated using their respective time markers. After the step of automatically associating, the subjective/sensor record is typically output in a written or computer-compatible form.

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The subjective record preferably includes an audio input from the patient in the form of a spoken diary entry. Other audio information such as unspoken patient sounds, sounds of distress, the words of bystanders, the words of caregivers, and the like may be similarly a part of the subjective record. The recorded patient audio
5 record may be in a digital or analog audio record form, and the recorded patient sensor record may be a digital sensor record or an analog sensor record. The subjective record may also or instead include written input from the patient. In either case, the patient input may be spontaneous, or may be prompted, for example responsive to the step of monitoring and recording the condition of the patient with the sensor. The
10 "subjective record" means input information that does not arise from objective measurements by sensors.

The present approach may be implemented using any operable apparatus. Preferably, there is provided a monitoring apparatus including a remote monitoring unit and a power supply connected to provide power to the remote monitoring unit.
15 The remote monitoring unit comprises at least one sensor associated with, and monitoring the condition of, the patient, with each sensor producing a sensor output. A subjective input device is operable to receive subjective input, such as audio or written information, and to provide a subjective-information output. A recording device records sensor output from the sensors and subjective-information output from
20 the subjective input device. A transceiver is in communication with the microprocessor. The recording device receives and records the subjective-information output with a subjective-information time marker, and the recording device receives and records the sensor output with a sensor time marker. The recorded subjective-information output is automatically temporally associated with the recorded sensor
25 output using the subjective-information time marker and the sensor time marker, to form an associated subjective/sensor record.

The monitoring apparatus may further include a subjective input device activating control, operable by the patient, which causes the subjective input device to become active so as to receive subjective information in audio or written form. It may
30 include a subjective input device activating control, operable remotely through the transceiver or locally by the remote monitoring unit, which causes the subjective input device to become active so as to receive subjective information. This latter approach,

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in which the subjective input device is activated independently of the patient, is particularly useful where the subjective input device is an audio receiver. The patient may spontaneously make diary entries or may be prompted to provide diary information. In the latter case, the patient may be prompted to make an oral or a
5 written entry in words selected by the patient, or the patient may be asked a series of questions to elicit information about specific symptoms or actions that may be most useful for medical personnel, or both. The prompts and questions may be provided by medical personnel and pre-programmed into the system.

The present approach records diary and other information from the patient and
10 third parties contemporaneously with events of interest. It ensures that the patient will not forget to make the diary entry, ensures a direct time correlation between the sensor record and the subjective record, and obtains information about activities and sensations of the patient as they occur rather than later when the patient's memory may not be accurate. The patient may be encouraged to make entries by prompts, if
15 the patient does not spontaneously make them as the events occur. Other features and advantages of the present invention will be apparent from the following more detailed description of the preferred embodiment, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention. The scope of the invention is not, however, limited to this preferred embodiment.

20

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block flow diagram of a preferred method for practicing the invention;

Figure 2 is a schematic drawing of a preferred apparatus used in conjunction
25 with the method of Figure 1; and

Figure 3 is a schematic depiction of a sensor output and an audio output as a function of time.

DETAILED DESCRIPTION OF THE INVENTION

30 Figure 1 illustrates a preferred approach to a method of organizing and correlating health information for a patient. A monitoring apparatus is provided, numeral 20. The monitoring apparatus may be of any operable type. The monitoring

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apparatus is preferably adapted to monitor an ambulatory patient who is not confined to a hospital under constant observation. The present approach is operable and useful in a controlled hospital environment, but it is most advantageously applied in the setting of the ambulatory patient.

5 A preferred monitoring apparatus 40 is illustrated in Figure 2. This monitoring apparatus 40 is generally of the type described in US Patent 5,959,529, whose disclosure is incorporated by reference, but modified as set forth herein. The monitoring apparatus 40 includes a central unit 42, a remote monitoring unit 44 that is associated with the ambulatory patient who is being monitored, and a power supply
10 46 that is associated with the patient and supplies power to the remote monitoring unit 44. (In Figure 2, the interconnections from the power supply 46 to the individual components of the remote monitoring unit 44 are not shown, to avoid clutter in the drawing.) The power supply 46 is typically in the form of a battery, but it may be a power source operating from the patient, such as a thermoelectric device, or a power
15 source operating from the environment, such as a photovoltaic device. The central unit 42 is normally at a fixed or movable location remote from the remote monitoring unit 44 and is capable of monitoring a number of different remote monitoring units carried by a number of individual patients.

The remote monitoring unit 44 includes at least one sensor 48 associated with
20 and monitoring the condition of the patient. Each sensor 48 produces a sensor signal 50, which is typically provided to a sensor controller 52 that conditions the sensor signal 50 and produces a sensor output 54 that serves as sensor-information input to the system. The sensor output 54 may be digital or analog in form. Digitizing, where
used, is performed by a conventional analog/digital converter in the sensor controller
25 52. The sensor 48 may be of any operable type. Examples include a heart monitor sensor, a blood pressure monitor sensor, a temperature monitor sensor, a brain wave sensor, a blood glucose sensor, a blood oxygen sensor, and a motion sensor. Such sensors 48 and their respective sensor controllers 52 are known in the art.

All or part of the remote monitoring unit 44 and the sensors 48 may be
30 implanted in the patient or external to the body of the patient.

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The remote monitoring unit 44 also includes a subjective input device of any operable type. Two types of subjective input devices are of particular interest and are discussed. A most preferred subjective input device is an audio receiver 56 operable to receive audio input through a microphone 58 from an ambient environment, and to
5 provide a subjective-information output 60 that serves as subjective-information input to the system. The subjective-information output 60 may be digital or analog in form. It may be unprocessed audio signals, or it may be processed through commercially available speech-recognition software. In this configuration, the remote monitoring unit 44 receives audio input from the ambient environment. The audio receiver 56
10 may optionally include an audio transmitter, and the microphone 58 may optionally include a speaker, so that two-way communication between the remote monitoring unit 44 and the patient may be established if desired.

An audio receiver activating control 62 activates the audio receiver 56 to enable it to receive an audio signal from the microphone 58 (and optionally transmit
15 an audio signal through the optional speaker). The audio receiver activating control 62 may be selectively operated by the patient in the form of a button, device, or spoken command. The audio receiver activating control 62 may instead or additionally be operated locally by the remote monitoring unit 44 itself through its internal logic, or remotely by the central unit 42 through a transceiver 64 of the
20 remote monitoring unit 44 that links the remote monitoring unit 44 with a similar transceiver in the central unit 42. The transceiver 64 is preferably a radio frequency transceiver such as a cellular telephone link, but it may instead be a telephone land line, a direct link, an infrared link, a microwave link, or the like.

A second type of subjective input device is a written-information receiver 56a,
25 working in conjunction with a keypad or other written information input device 58a and a written receiver activating control 62a. As in the case of the audio receiver 56, the written information receiver 56a may have an output capability as well, operating through a display visible to the patient. The prior discussion of the elements 56, 58, and 62 is incorporated here, modified to apply to written input/output rather than
30 audio input/output. The output 60 in general is a subjective-information output.

The features of the audio and written subjective input devices may be used interchangeably as appropriate for effective operation and communication. For

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example, even in the case of a written-information receiver, the output to the patient may be in audio form so that audio prompts and questions may be spoken to the patient to elicit written input. Audio and written input are herein collectively termed "subjective information" because they include non-sensor, non-quantitative
5 information from the patient and possibly from bystanders such as laypeople observers and/or on-the-scene medical personnel. In another example, the patient may be prompted with a written menu of choices for subjective patient input, and the actual subjective patient input may be either written or oral.

The remote monitoring unit 44 includes a time reference source 66 that
10 provides a sensor time marker 68 to the sensor output 54 and a subjective-information time marker 70 to the subjective-information output 60. The sensor time marker 68 is associated with the sensor output 54, and the subjective time marker 70 is associated with the subjective-information output 60. The time markers 68 and 70 are preferably absolute time values provided by a clock in the time reference source 66. The time
15 markers 68 and 70 need not be absolute time markers, but must have a known relation to each other. However, so that sensor and subjective information of interest may be correlated with the outside world, it is preferred that an absolute time value be used.

The remote monitoring unit 44 further includes a recording device 72 operable to record the time-marked sensor output 54 from the sensor 50 (as the sensor
20 information input) and the time-marked subjective-information output 60 (as the subjective-information input) from the audio receiver 56 and/or the written receiver 56a. The recording device 72 may be a stand-alone device under control of a microprocessor/central processing unit built into the remote monitoring unit 44. The recording function may instead be accomplished by the microprocessor/central
25 processing unit and its associated memory in the case that the sensor output 54 and the subjective-information output 60 are digitized. For generality, the recording device 72 is depicted as having a first unit 74 that receives and records the time-marked sensor output 54 and a second unit 76 that receives and records the time-marked subjective-information output 60, but the two units 74 and 76 may be implemented in
30 a single device.

In the preceding description, the time reference source 66 was depicted as marking the sensor output 54 and the subjective information output 60 prior to their

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reaching the recording device 72. Equivalently, they may be marked by and within the recording device 72 using separate time markers or a single time marker. All that is required of the time marking is that the sensor output 54 and the subjective-information output 60 be capable of temporal association either in the recording device 72 or elsewhere. It is not necessary to use time markers if the sensor output 54 and the subjective-information output 60 are recorded on the same time scale, so that the sensor output 54 and the subjective-information output 60 may still be associated and correlated. However, it is generally preferable to use time markers so that the sensor output 54 and the subjective-information output 60 may be correlated with other events external to the remote monitoring unit 44.

Returning to the discussion of Figure 1, the monitoring apparatus 40 of Figure 2 is operated, numeral 22, to receive and record the subjective-information output 60, numeral 24, and to receive and record sensor output(s) 54, numeral 26. Figure 3 illustrates a typical sequence of events for the sensor output 54 and the subjective-information output 60, although the present method is not limited to this sequence of events. The sensor output 54 initially is normal in a first period 80. At time 82, the sensor output 54 deviates in some fashion from the normal sensor output, which typically is identified by the sensor output exceeding a threshold defined by medical personnel. The audio receiver 56 or the written receiver 56a is activated at time 84. The subjective-information output 60 is thereafter received and recorded as described. The subjective-information output 60 typically includes the patient's spoken contemporaneous description of the perception of events and sensations, and it may also include other audio information as well such as sounds in the environment and third party comments. Sensor time markers 86 and subjective-information time markers 88 are respectively applied to the sensor output 54 and the subjective-information output 60 in the manner discussed previously, so that they may later be temporally associated.

The time 84 of the start of the subjective-information output 60 may be prior to, the same as, or after the time 82 of the start of the abnormality of the sensor output 54. For example, the patient may operate the audio receiver activating control 62 and indicate an unusual sensation or record a particular physical activity prior to or at the same time as the start 82 of the departure from normality in the sensor output 54. The

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patient may instead feel nothing unusual prior to and at the time 82 of the start of the abnormality of the sensor output 54. In that case, the patient may optionally be prompted (numeral 28 of Figure 1) to begin a diary entry as with a verbal prompt 90 delivered after the time 82 of or after the start of the abnormality of the sensor output

5 54. The prompting is typically accomplished in the optional case where the microphone 58 is provided with the speaker, and the audio receiver 56 acts as a transmitter as well. In that case, the patient may be prompted to operate the audio receiver activating control 62, or the audio receiver activating control 62 may be automatically activated locally by the remote monitoring unit 44 or remotely by the

10 central unit 42. The remote monitoring unit 44 and/or the central unit 42 typically contain logic processors to detect abnormalities in the sensor output 54, and may then activate the audio receiver activating control 62 (without any action by the patient) and prompt the patient to begin speaking a diary entry. The prompt 90, if any, is preferably initiated locally by logic in the remote monitoring unit 44 itself, to avoid

15 the time delay in establishing a communication link with the central unit 42.

Once the time-marked sensor output 54 and the time-marked subjective-information output 60 are recorded in the recording device 72, they are temporally associated through the respective time markers 86 and 88, numeral 30, to form a subjective/sensor record. (That is, the outputs 54 and 60 are associated through the

20 presence of the respective time markers 86 and 88, hence the use of the term "temporally". The term "temporally" does not suggest that the association is only for a short time, i.e., "temporarily".) The associating step 30 may be accomplished in the remote monitoring unit 44, and the combined subjective/sensor record transmitted, numeral 32, to the central unit 42 through the transceiver 64. The separate record of

25 the sensor output 54 and the record of the subjective-information output 60 may instead be individually transmitted, numeral 32, to the central unit 42 through the transceiver 64, and the associating step 30 performed at the central unit 42. Thus, the step 30 may precede step 32, as illustrated, or follow step 32.

The association, analysis, and logic-performing capabilities of the monitoring

30 apparatus 40 may be distributed between the central unit 42 and the remote monitoring unit 44 in any operable fashion. These functions may be placed in the remote monitoring unit 44, so that the central unit 42 serves primarily as a transceiver

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terminal, or these functions may be placed in the central unit 42 so that the remote monitoring unit 44 serves primarily as a transceiver terminal. More typically, the functions are allocated between the central unit 42 and the remote monitoring unit 44 in a fashion that provides the best combination of functionality and economics for the system.

The associated subjective/sensor record is optionally output, numeral 34, from the central unit 42 to an output device 43, numeral 34. The output device 43 may be a local device at the central unit 42, such as a video display or printer and/or an audio output device, or a storage device at the central unit 42. It may instead be a remote link such as a land-line telephone link to the patient's physician. The output step 34 may occur virtually simultaneously with the events as they occur or have only a short time delay from the events, after the communication through the transceiver 64 is established, so that a person reviewing the records may assist the patient in responding to an event with a communication back to the patient through the transceiver 64. The knowledge by the patient that there is assistance being rendered and that the patient is not alone often provides comfort to the patient and calms the patient. The sensor and audio records may instead or additionally be played at a later time for more complete diagnosis of the events. The contemporaneous response is appropriate for an emergency so that medical personnel may diagnose the patient, and the delayed response is appropriate for a routine or non-emergency abnormality or for after-the-fact evaluation of the emergency. In a typical case, the sensor output 54 is displayed on a screen or printed, and the subjective-information output 60 is displayed on a screen, printed, or output as an audio signal so that a person analyzing the subjective/sensor record may readily hear and correlate the sounds with the sensor output.

The present approach thus provides a direct correlation of subjective-information output and sensor output of a patient. The correlated information is highly useful, particularly in the case of an ambulatory patient, to respond to emergencies and to provide diagnosis. As discussed previously, it may be applied in the case of a monitoring apparatus 40 such as described above. It may also be applied in other types of monitoring situations and monitoring apparatus, for example Holter monitoring, Event monitoring, and Event Loop Recorder monitoring, ECG Stress

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Testing systems, implantable ECG monitors/recorders, implantable cardiac defibrillators, external cardiac defibrillators, pacemakers, and sleep apnea monitors.

Although a particular embodiment of the invention has been described in detail for purposes of illustration, various modifications and enhancements may be
5 made without departing from the spirit and scope of the invention. Accordingly, the invention is not to be limited except as by the appended claims.

CLAIMS

What is claimed is:

1. A method of organizing and correlating health information for a patient, comprising the steps of:

providing a monitoring apparatus including

a remote monitoring unit, the remote monitoring unit comprising

at least one sensor associated with and monitoring the condition of the patient, each sensor producing a sensor output,

a subjective-information receiver operable to receive subjective-information input and to provide a subjective-information output,

a recording device operable to record sensor output from at least one sensor and the subjective-information output from the subjective-information receiver, and

a transceiver in communication with the recording device, and;

a power supply connected to provide power to the remote monitoring unit;

the recording device receiving and recording the subjective-information output with a subjective-information time marker;

the recording device receiving and recording the sensor output with a sensor time marker; and

automatically temporally associating the recorded subjective-information output with the recorded sensor output using the subjective-information time marker and the sensor time marker, to form an associated subjective/sensor record.

2. The method of claim 1, wherein the subjective-information input is an audio input.

3. The method of claim 1, wherein the subjective-information input is a written input.

4. The method of claim 1, wherein the monitoring apparatus further includes

a subjective information receiver activating control, operable by the patient, which causes the subjective-information receiver to become active so as to receive subjective-information.

5. The method of claim 1, wherein the monitoring apparatus further includes

a subjective-information receiver activating control, operable remotely through the transceiver, which causes the subjective-information receiver to become active so as to receive subjective information.

6. The method of claim 1, wherein the monitoring apparatus further includes

a subjective-information receiver activating control, operable by the remote monitoring unit, which causes the subjective-information receiver to become active so as to receive subjective information.

7. The method of claim 1, wherein the step of receiving and recording the subjective-information output produces a digital subjective-information record and the step of receiving and recording sensor output produces a digital sensor record.

8. The method of claim 1, wherein the step of receiving and recording the subjective-information output produces an analog subjective-information record and the step of receiving and recording sensor output produces an analog sensor record.

9. The method of claim 1, wherein the transceiver is a radio frequency transceiver.

10. The method of claim 1, including an additional step, after the step of automatically temporally associating, of
outputting the subjective/sensor record.

11. The method of claim 1, wherein the recording device comprises a single unit operable to record both sensor output and subjective-information output.

12. The method of claim 1, wherein the monitoring apparatus further includes

a central unit operable to communicate with the recording device through the transceiver.

13. A method of organizing and correlating health information for a patient, comprising the steps of:

recording a subjective input from the patient as a recorded patient subjective-information record with a subjective-information time marker;

monitoring and recording the condition of the patient with a sensor as a recorded patient sensor record with a sensor time marker; and

automatically associating the recorded patient subjective-information record and the recorded patient sensor record through the respective subjective-information time marker and the sensor time marker to produce a subjective/sensor record.

14. The method of claim 13, wherein the subjective-information input is an audio input.

15. The method of claim 13, wherein the subjective-information input is a written input.

16. The method of claim 13, wherein the recorded patient subjective record is a digital subjective record and the recorded patient sensor record is a digital sensor record.

17. The method of claim 13, including an additional step, after the step of automatically associating, of

outputting the subjective/sensor record.

18. The method of claim 13, wherein the step of recording a subjective input includes the step of

prompting the patient to make the subjective input.

19. The method of claim 13, wherein the step of recording a subjective-information input includes the step of

prompting the patient to make the subjective input responsive to the step of monitoring and recording the condition of the patient with the sensor.

20. A method of organizing and correlating health information for a patient, comprising the steps of:

recording a subjective input from the patient as a recorded patient subjective-information record;

monitoring and recording the condition of the patient with a sensor as a recorded patient sensor record; and

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automatically associating the recorded patient subjective-information record
and the recorded patient sensor record.

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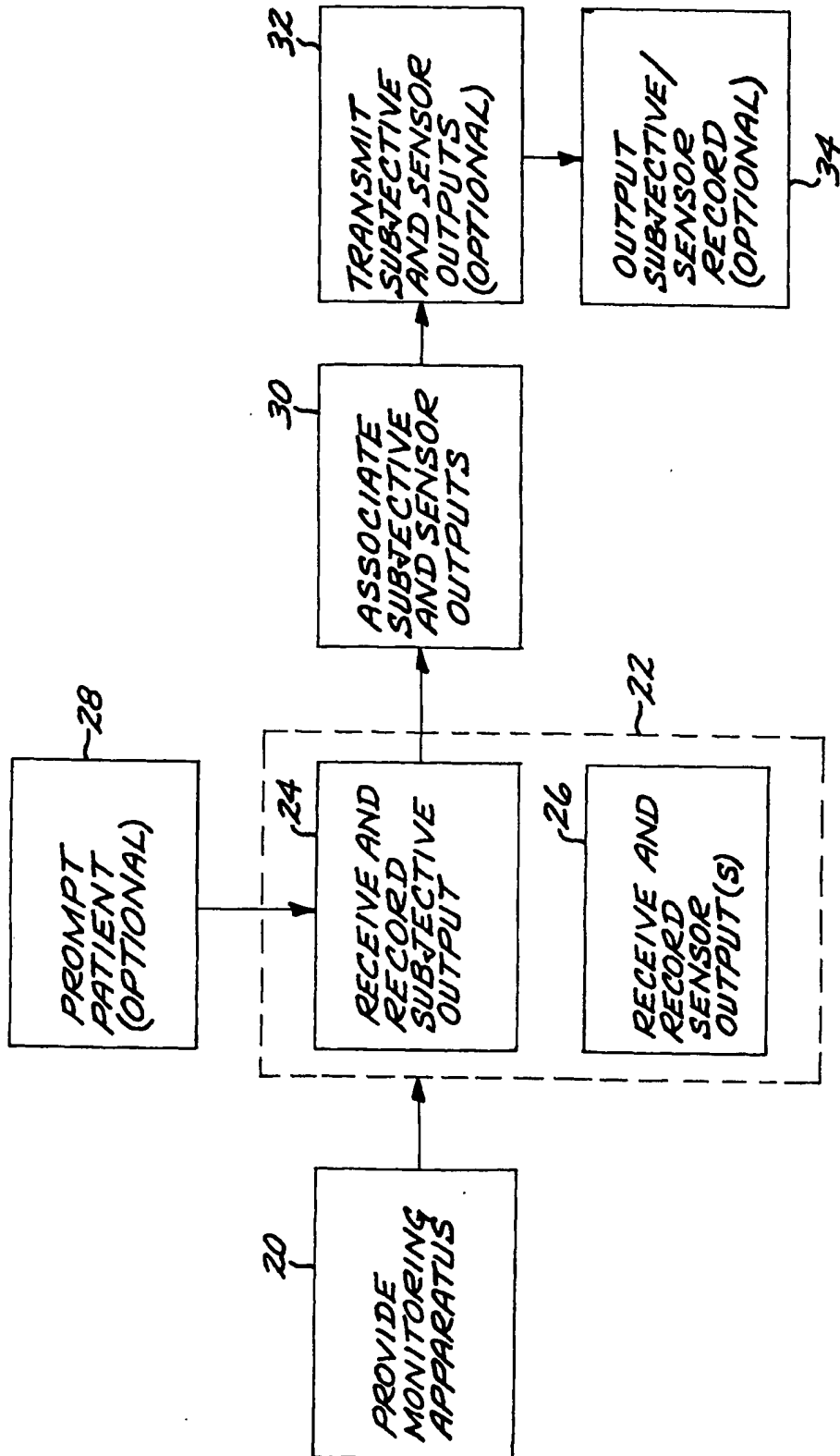
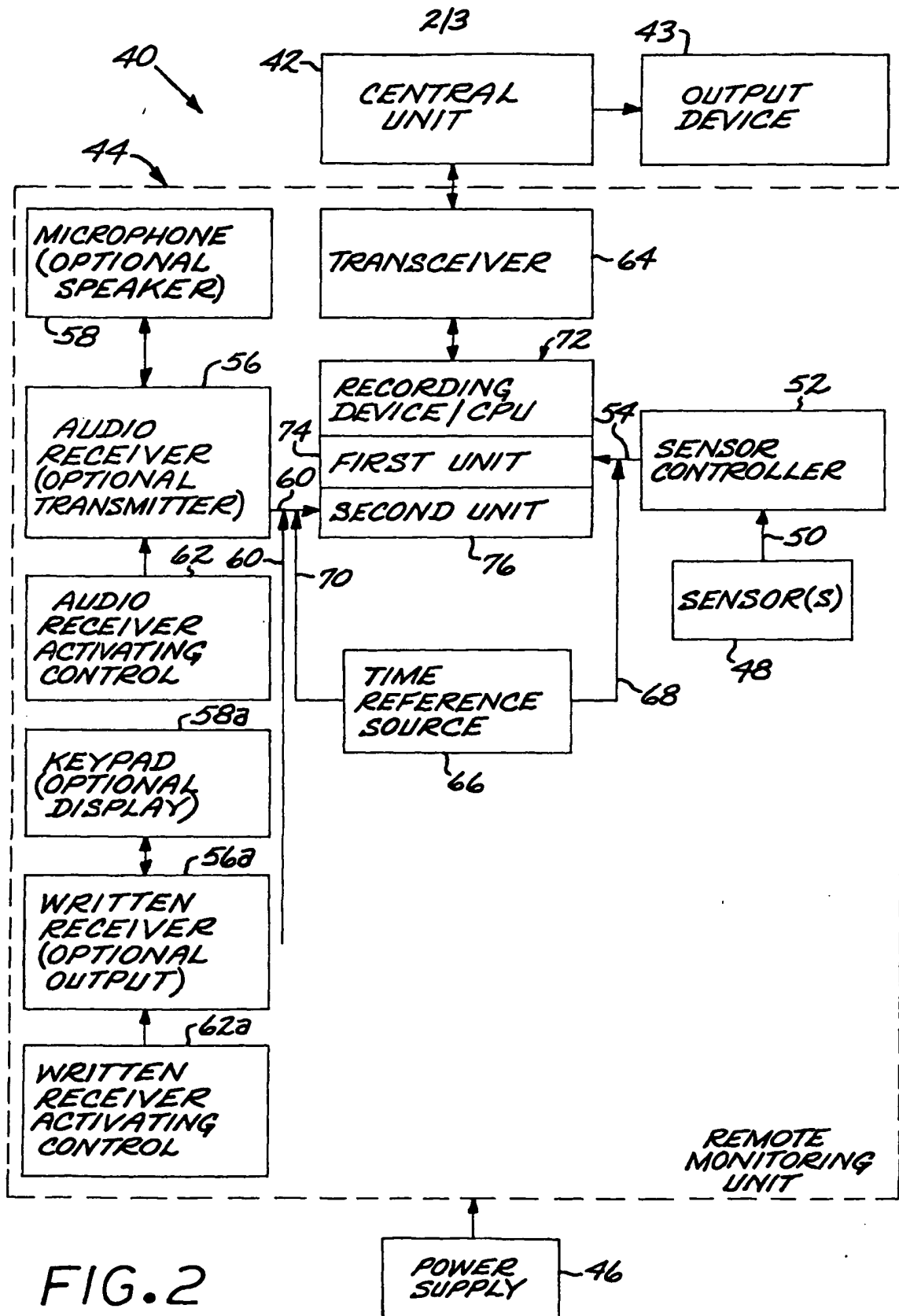


FIG. 1



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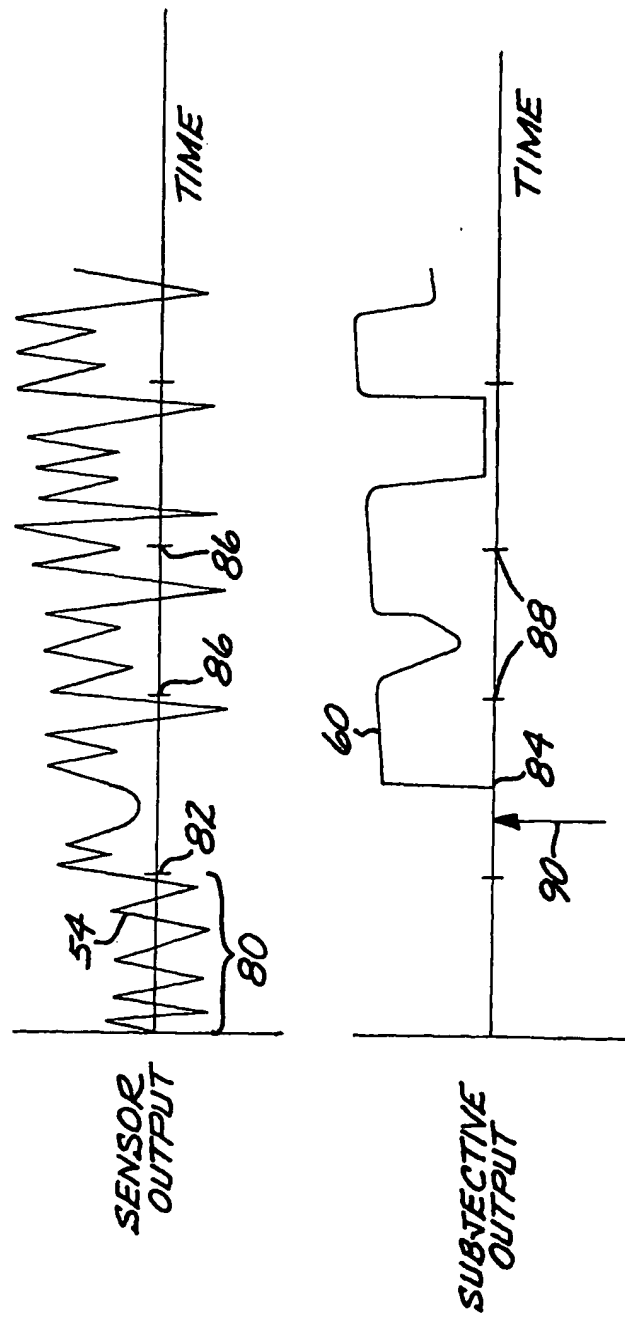


FIG. 3

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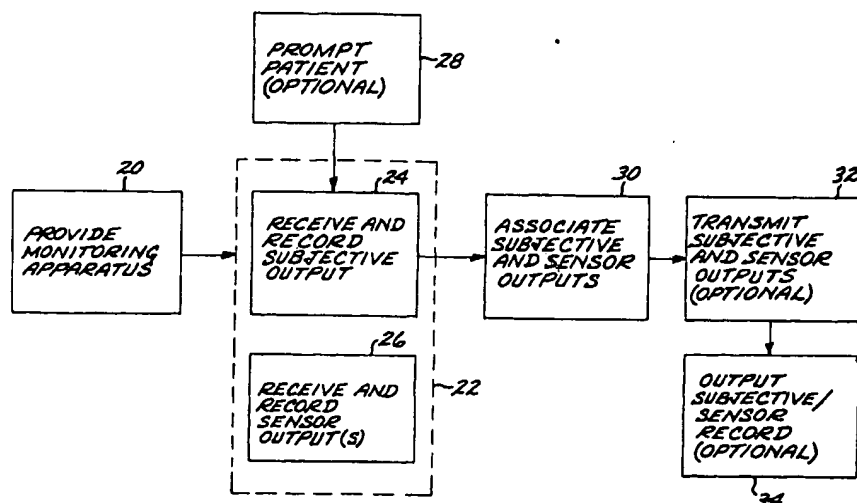
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(54) Title: CORRELATION OF SENSOR SIGNALS WITH SUBJECTIVE INFORMATION IN PATIENT MONITORING



(57) Abstract: Health information for a patient is organized and correlated by recording a subjective-information input from the patient as a recorded patient subjective-information record, monitoring and recording the condition of the patient with a sensor as a recorded patient sensor record, and automatically associating the recorded patient subjective record and the recorded patient sensor record. The association may be accomplished through the use of respective subjective-information time markers and sensor time markers to produce a subjective/sensor record.

WO 02/086792 A3

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 02/12871

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 96 25877 A (BRIGHAM AND WOMEN'S HOSPITAL) 29 August 1996 (1996-08-29)</p> <p>page 3, line 16 -page 4, line 15 page 9, line 19 -page 12, line 4 page 16, line 8 -page 17, line 4 page 52, line 15 -page 60, line 17 claims 1,18-28,59-77 figures 1,3,4</p> <p style="text-align: center;">--- -/--</p>	<p>1,3-7, 10-13, 15-20</p>

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

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O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Z document member of the same patent family

Date of the actual completion of the international search

21 February 2003

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 02/12871

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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